

REMARKS/ARGUMENTS

Applicants submit that the claims, as amended, highlight the discovery that members of the *Serpens* genus play an important role in Papillomatous Digital Dermatitis ("PDD") and, perhaps more importantly, in eliciting an immunogenic response (not limited to eliciting protective antibodies) that facilitates resistance to the PDD pathogen. Thus, the present claims encompass various species of the *Serpens* genus as part of an immunogenic composition and not as species of the *Serpens* genus per se.

Rejections under 35 U.S.C. § 112, ¶ 1 - Enablement

Claims 18 and 20-26 were rejected based on a lack of enablement.

Applicants have cancelled claims 18, 21, 22, 23, 25 and 26 and amended claims 20 and 24. Applicants submit that the above rejection has either been rendered moot by these amendments or is addressed by the following remarks.

Applicants have removed the words "for the prevention and treatment of Papillomatous Digital Dermatitis" from claims 20 and 24. The examiner noted that these words add "a requirement of demonstrating protective immunity." Although the examiner agreed with Applicants that it is routine to identify "immunologically active portions" of bacterial species which "can elicit or react with an antibody," he noted that "it does not follow that the resulting immune response will be one of protection." The claims, as amended, encompass an immunogenic composition which elicits any immune response and not only the "protective immunity" of a vaccine. (See, e.g., page 25 of the specification.)

Based on the amendments and the above remarks, Applicants request that the Examiner withdraw the enablement rejection as to claims 20 and 24.

Rejections under 35 U.S.C § 102

The examiner also rejected claims 18, 20 and 24, asserting that these claims are anticipated by Hespell. Applicants respectfully traverse this amendment.

Applicants have canceled claim 18 and amended claims 20 and 24.

For a reference to be anticipatory, it must disclose each and every element of the claims at issue. Hespell does not disclose every element of claim 20 or of claim 24.

Claim 20 (as amended and even before amendment) includes a "veterinarily acceptable diluent or carrier" element. Hespell does not disclose this element. Applicants agree with the Examiner's statement that Hespell discloses "culturing *Serpens flexibilis* in a lactate broth which contains 100 ml of distilled water." Lactate broth, however, is not a veterinarily acceptable diluent or carrier. Water, as an ingredient of lactate broth, is not a veterinarily acceptable diluent, as none of the other ingredients of the broth disclosed in Hespell are veterinarily acceptable diluents and thus would contaminate the water. Furthermore, Hespell does not disclose culturing, storing or handling of *Serpens flexibilis* in distilled water without other ingredients. Because the Hespell reference does not disclose each and every element of claim 20, it does not anticipate the claim.

Although the examiner rejected claim 24, which, before amendment, was drawn to an "attenuated" bacteria of the genus *Serpens*, the examiner also stated on page 6 of the office action that "none of the rejected claims recite that the *Serpens* must be attenuated." To better comport with the language of the specification, Applicants have amended claim 24 to refer to "killed" bacteria of the genus *Serpens* rather than "attenuated" bacteria. Hespell does not teach an "attenuated" or "killed" bacteria of the genus *Serpens*. Because Hespell does not disclose each element of claim 24, it does not anticipate the claim.

Based on the foregoing amendments and remarks, Applicants request that the examiner reconsider and withdraw his rejection of claims 20 and 24 under 35 U.S.C. § 102.

Rejections under 35 U.S.C. § 112, ¶ 1 – New Matter

Claims 21-23 and 25-26 are rejected as containing new matter. Applicants have canceled these claims, rendering this rejection moot.

Rejection under 35 U.S.C § 112, ¶ 1 – Written Description

The Examiner further rejected claims 18 and 20-26, asserting that the application does not adequately describe the *Serpens* genus, as "a *Serpens* HBL-112 strain alone is insufficient to describe the genus." Applicants, however, have disclosed two members of the genus, *Serpens* spp. HBL-112 and *Serpens flexibilis*, both of which will function as part of an immunogenic composition. The characteristics of these species, which are thoroughly described in the text and tables of the specification, adequately represent the characteristics of the genus, such that one of ordinary skill in the molecular biological arts would be able to identify another member of the species. Indeed, those of ordinary skill in the art are accustomed to classifying bacteria based on the types of morphological and biochemical properties disclosed in the application, as these are the types of properties that are disclosed in Bergey's Manual of Determinative Bacteriology to characterize bacteria.

In addition, the claims are directed to an immunological composition that includes as a limitation bacterial species of the *Serpens* genus. Thus, the claims encompass Applicants' discovery that species of the *Serpens* genus elicit an immune response that increases resistance to PDD. Because multiple bacterial species of the *Serpens* genus, as well as their role in an immunogenic composition, have been adequately described in the specification and claims,

Applicants request that the written description requirement be reconsidered and withdrawn.

Based on the foregoing amendments and remarks, Applicants respectfully submit that the application is now in condition for allowance. Included is a fee in the amount of \$475.00 for a 3 month extension. Any additional fees required by this submission may be charged to deposit account 50-2767. If the Examiner has any questions regarding this communication or feels that an interview might facilitate prosecution of the application, he is invited to contact the undersigned at (916) 444-3900.

Respectfully submitted,

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